

**SUMMARY OF THE  
ON-SITE ASSESSMENT COMMITTEE MEETING  
NOVEMBER 19, 2002**

The On-site Assessment Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met on Tuesday, November 19, 2002, at 1:30 p.m. Mountain Standard Time (MST) as part of the Eighth NELAC Interim Meeting (NELAC 8i) in Santa Fe, NM. Chairperson Mr. Alfredo Sotomayor of the Wisconsin Department of Natural Resources led the meeting. A list of action items is given in Attachment A. A list of participants is given in Attachment B. The purpose of the meeting was *to discuss proposed definitions for the NELAC Glossary, to present on-site assessment issues raised in NELAC training sessions, to report on the pilot assessors' electronic forum, and to solicit input on other proposed changes to Chapter 3.*

**INTRODUCTION**

Following a review of the meeting ground rules and agenda by the session's facilitator, Mr. Sotomayor welcomed attendees. The members of the committee introduced themselves. Mr. Sotomayor briefly reviewed the committee's activities since the eighth NELAC annual meeting (NELAC 8). Since NELAC 8, the committee has planned and delivered an electronic forum for NELAC assessors. The forum was presented on October 15, 2002. The committee has also directed its attention to developing proposed NELAC glossary definitions for "deficiency," "finding," and "observation."

**PROPOSED DEFINITIONS FOR NELAC GLOSSARY**

Dr. Frederic Siegelman delivered a presentation on the committee's proposed NELAC glossary definitions on behalf of Mr. Jack Hall, who was unable to attend the meeting. He explained that the presentation was based on the committee's work in response to an assessor survey requesting information on reporting and recording practices during and after assessments and Mr. Hall's presentation at the assessors' electronic forum. The committee's effort is an attempt to clarify the definitions and provide a starting point for further discussions within NELAC. The current definitions for "finding" and "deficiency" do not reference the NELAC Standards and may not reflect what assessors are calling findings or deficiencies. The On-site Assessment Committee has developed definitions, therefore, for "finding" and "observation." "Deficiency" is proposed to be the same as "finding."

In addition to the committee's proposed definitions, Dr. Siegelman presented alternate definitions for discussion and comparison. He presented International Organization for Standardization (ISO) audit definitions, U.S. Environmental Protection Agency (EPA) technical system assessment definitions, and American National Standards Institute/American Society for Quality Control (ANSI/ASQC) audit definitions

Following the presentation, the committee opened the issue to discussion from the floor. Discussion was spirited. It was suggested that having only definitions for "finding" and "observation" is limiting. It was also noted that the word "significant" is not defined and that

different assessors have different philosophies on how to identify “findings” and “deficiencies.” It was suggested that the key to the definition of “finding” is data defensibility.

There was discussion of tiered definitions, with several attendees expressing a preference for the U.S. EPA technical system assessment definitions. Attendees were generally in favor of tiered definitions that would take into consideration the effect of nonconformance on data quality and defensibility. A member of the committee noted that members of the NELAC community come from different backgrounds where these terms are used in a variety of ways and, consequently, are having difficulty coming to consensus on this key issue.

There was substantial discussion of what makes a finding significant and of how a laboratory would know that an observation must be corrected. It was noted that the current definitions require assessors to make judgement decisions as to findings and deficiencies. It was suggested that the significance of a finding relates to the difference between a requirement and the practice of the requirement as observed during the assessment. The committee pointed out that the current format for assessment reports requires assessors to reference the NELAC Standards.

An alternate definition for “observation” was proposed from the floor as follows:

Observation: a statement describing an adverse condition that does not have a negative effect on data quality. The laboratory must fix the condition but is not required to document the fix.

It was noted that the definition proposed from the floor implies that assessors will be able to decide which adverse conditions do not have a negative effect on data quality.

A representative from an approved National Environmental Laboratory Accreditation Program (NELAP) accrediting authority (AA) indicated that his organization operates from an enforcement perspective and, therefore, cannot make recommendations. The AA’s assessment reports contain nothing but facts. The assessors report only findings, whether they be critical or minor. In response, the committee noted that Section 3.7.2 h of the NELAC Standards does require the inclusion of comments and recommendations in assessment reports. The commenter acknowledged the requirement but reiterated that his program precludes the inclusion of recommendations on the assessment report.

It was suggested that issues that do not affect data quality should not be a requirement of the NELAC Standards. It was suggested that the committee’s focus should be on modifying the standards rather than putting assessors in the position of making distinctions. The committee noted that the process for changing NELAC Standards is not geared toward accomplishing the change through a modification in glossary definitions.

Dr. Siegelman summarized the input provided by attendees, as follows:

- If an assessor finds that a laboratory does not meet a requirement that is included in the NELAC Standards, then it is a “finding.” The finding must be reported and it must be corrected.

- Attendees at NELAC 8i are in support of tiered definitions for “finding,” with the understanding that there may be critical findings that prevent the issuance of an accreditation certificate and less serious findings that may be corrected over time.
- The process for changing the NELAC Standards is not geared toward accomplishing the change through glossary definitions.
- Laboratories recognize the positive value of assessor comments and recommendations. Assessors can pass along observations to help laboratories improve their performance. Laboratories and their stockholders value best practices information communicated through audit reports that management will read.
- In some regulatory environments, it is difficult to pass along best practices information. Some regulators cannot make recommendations; they can make comments only.

Following Dr. Siegelman’s summary, Mr. Sotomayor thanked attendees for their input. He indicated that the committee would review the comments made at NELAC 8i and craft a proposal for presentation at the Ninth NELAC Annual Meeting (NELAC 9).

#### **ON-SITE ASSESSMENT ISSUES IDENTIFIED IN TRAINING SESSIONS**

Ms. Marlene Moore led discussion of assessment issues identified in training sessions conducted over the past year. She noted that not all of the issues pertain to the On-site Assessment Committee and that she will compile the issues and provide them to the appropriate NELAC committees. Ms. Moore identified the following issues:

Issue 1 - Implementation of fields of testing as defined in Chapter 1 of the NELAC Standards - Assessor training is currently based on the 2000 NELAC Standards. As NELAC transitions to the 2001 NELAC Standards in July 2003, there are questions regarding how to implement the fields of testing as defined in Chapter 1. Clarification of the accreditation scheme will require coordination between the NELAC Program Policy and Structure, Proficiency Testing, On-site Assessment, and Quality Systems Committees.

Issue 2 - Current version of NELAC Standards - Laboratories and accrediting authorities are having trouble keeping up with the current version of the NELAC Standards. It is especially challenging for small organizations. This is a point of confusion which may be addressed as NELAC moves to a two-year process of standard implementation.

Issue 3 - Questions on time lines for grandfathering (i.e., technical director and assessors) - Ms. Moore noted that Section 3.2.1 of the NELAC On-site Assessment Standard (Basic Qualifications) states that a NELAC assessor must complete the NELAC Basic Training Course and perform four NELAC assessments. This poses an interesting question for new AAs as to how their assessors can have performed four NELAC assessments if the AA has not been an AA. Ms. Moore suggested that the On-site Assessment Committee needs to revisit the issue of how new AAs can meet training requirements for assessors.

Issue 4 - Assessment Documents - Ms. Moore noted that Section 3.4.4 of the NELAC Standards (Assessment Documents) lists several documents that must be provided to laboratory management in conjunction with an on-site assessment. She noted that several assessors had been unsure of whether their AA had a Conflict of Interest (COI) Form. Several questions about the required assessment documents have been raised in training sessions. Among the questions raised are the following: If the forms are required by the NELAC Standards, should the NELAP accrediting authorities have uniform forms? Are the forms presented before the start of the assessment, during the assessment, throughout the assessment? Ms. Moore recommended that the On-site Assessment Committee revisit Section 3.4.4. She also requested input from the laboratory community on this issue.

Issue 5 - Follow-up on-site assessments - Ms. Moore noted that Section 3.3.2 of the NELAC Standards addresses follow-up assessments to determine whether laboratories have completed corrective action in response to deficiencies noted by an assessor. She indicated that there is inconsistency among the AAs in policies and procedures for follow-up assessments because the NELAC Standards do not clearly direct this process. There is nothing in Chapter 3 or Chapter 4 that indicates that laboratories must submit documentation of corrective action by the intended date. It has been left up to the AAs to interpret the standards on this issue. Ms. Susan Wyatt, chair of the NELAC Accreditation Process Committee, indicated that her committee has also discussed this issue. She noted that the Accreditation Process Committee will propose a change to Section 4.1.3 g of the NELAC Standards to require laboratories to implement and maintain corrective actions. Ms. Moore noted that resolution of the issue will require coordination between the On-site Assessment and Accreditation Process Committees. In response, Ms. Wyatt expressed her commitment to working with the Proficiency Testing and On-site Assessment Committees on the issue.

## **REPORT ON PILOT ASSESSORS' FORUM**

Mr. Sotomayor presented a report on the pilot assessors' electronic forum delivered on October 15, 2002. The forum was delivered via Internet (visual materials) and teleconference lines (audio) and was co-sponsored by the On-site Assessment Committee, the U.S. EPA Office of Solid Waste and Environmental Response (OSWER), and the U.S. EPA Technology Innovation Office. Mr. Sotomayor noted that the materials from the electronic forum presentations are archived at the website at <http://www.clu-in.org/conf/tio/assessorsforum/>.

The goals of the assessors' forum to the NELAC Standards:

- to review changes to the NELAC Standards, thereby providing refresher training,
- to deliver presentations on topics of interest to assessors,
- to provide a forum for the exchange of ideas,
- to evaluate the suitability of the forum presentation medium,
- and, ultimately, to promote the consistency of on-site assessments.

The forum agenda included significant changes to the NELAC Standards (presented by Dr. Siegelman), an evaluation of quality systems (presented by Ms. Moore), use of the Chapter 5 checklist (presented by Mr. Charles Dyer), reporting and recording findings (presented by Mr.

Jack Hall), and selecting raw data for review. Approximately ten minutes were provided after each topic for a question and answer session.

Mr. Sotomayor presented some statistics on the forum. He noted that 137 individuals from 25 cities participated in the forum on 36 telephone lines. All NELAP accrediting authorities were represented. In addition to the NELAP accrediting authorities, representatives from Iowa, Indiana, Minnesota, Nevada, Oklahoma, Texas, Virginia, Vermont, the U.S. EPA Offices of Ground Water and Drinking Water, Solid Waste and Environmental Resources, and Environmental Information, U.S. EPA Regions 2 and 9, the Department of Defense, and RTI participated in the forum. The cost of the forum was under \$2,000.00. A repeat presentation of the same forum materials would cost about \$350.00.

Finally, Mr. Sotomayor shared some of the feedback received from forum participants. Feedback was generally positive. Participants agreed that instructors were knowledgeable and that their presentations were easy to follow. There was some feedback indicating that participants would like more time for questions and answers. Mr. Sotomayor suggested that the most telling bit of feedback was that the majority of participants indicated that they would recommend the forum to other environmental professionals.

The committee learned much from the planning and delivery of the electronic forum. The pilot was deemed a success. The committee identified areas of success and areas for improvement. The electronic medium was judged to be a viable medium for communication among assessors. The committee noted that the forum content could be targeted to different audiences and that interaction and exchange between assessors is of paramount importance.

Several attendees who had participated in the electronic forum offered their thanks to the On-site Assessment Committee. Some states indicated that they would use a similar format for future state training programs. Other states noted that their technical assessors do not get to travel to conferences and that the electronic forum was a good opportunity for those assessors to hear about the NELAC Standards from larger audience than their daily managers.

In conclusion, Mr. Sotomayor noted that face-to-face forums, while preferable, are more costly than electronic forums. In the next few months, the On-site Assessment Committee will be considering different ways for consistent funding and delivery of the forum. The committee hopes to have something to report at NELAC 9.

### **CHANGES TO CHAPTER 3**

Mr. William Ingersoll led a discussion of changes to Chapter 3 of the NELAC Standards. Noting that the committee had no formal proposed changes, he opened the issue to discussion from the floor.

There was some discussion of personnel qualifications for laboratory technical directors outlined in Section 4.1.1.2 of the NELAC Standards. A commenter noted that the 2002 standards provide for a waiver of education and experience for a technical director holding a valid treatment plant operator certificate. The commenter suggested that the holder of a valid treatment plant operator

certificate may not have the necessary science background for supervising a laboratory. In response, the committee noted that procedures vary from state to state and that in many states the laboratory supervisor does not necessarily have to be conversant with the analysis. The committee also noted that Section 3.2.1 of the NELAC Standards indicates that assessors must have a working knowledge of and be conversant with the tests for which accreditation is sought.

It was suggested that the On-site Assessment Committee consider some requirement for hands-on laboratory experience for assessors. Mr. Ingersoll noted that the committee could revisit Section 3.2.1 to strengthen the standard to require hands-on experience in the laboratory. Another commenter noted that assessor training cannot teach technical expertise to the level of test method accreditation and that assessors are supposed to be technical experts or at least peers of the laboratory analysts.

Although no other changes to Chapter 3 were proposed from the floor, Mr. Ingersoll pointed out sections of the chapter that may address the issues reviewed by Ms. Moore earlier in the meeting. He noted that Section 3.2.1 b addresses questions on timelines for grandfathering. He also noted that Appendix C, Section C6, addresses follow-up assessments.

## **EXPERIENCES AND CONCERNS WITH ASSESSMENTS**

The committee solicited input from attendees on their personal experiences and concerns with on-site assessments. There was minimal feedback from the audience. Noting that it is important to monitor assessor performance, a commenter encouraged the committee to reinforce the requirement that assessors leave an evaluation form with laboratories. There was also moderate discussion of the requirement for a COI Form. Some accrediting authority representatives suggested that COI information is not information that states should be required to submit to laboratories.

## **UPDATE ON NELAC CHAPTER 5 CHECKLIST**

Mr. Charles Dyer reported that an update of the Chapter 5 checklist had been given to the On-site Assessment Committee and the accrediting authorities for their review. Mr. Dyer noted that he hoped to post the revised checklist on the NELAC website by February 2003. He indicated that he had received requests that his annotated copy of the checklist be posted on the website in addition to the “clean copy.” The committee was in agreement that it would be beneficial to post the annotated copy of the checklist on the NELAC website so that users could more readily see what had been changed.

## **CONCLUSION**

There being no further business to discuss, Mr. Sotomayor thanked all in attendance for their participation. He indicated that the committee would discuss the issues raised in the meeting and that they would revisit many of the issues at NELAC 9. Mr. Sotomayor adjourned the meeting shortly before 5:00 MST.

**ACTION ITEMS  
ON-SITE ASSESSMENT COMMITTEE MEETING  
NOVEMBER 19, 2002**

<b>Item No.</b>	<b>Action</b>	<b>Date to be Completed</b>
1.	Committee will review feedback received at NELAC 8i to draft revised proposed glossary definitions for “finding” and “observation” for presentation at NELAC 9.	NELAC 9
2.	Committee will address assessment issues raised in NELAC training sessions and summarized by Ms. Moore.	NELAC 9
3.	Committee will consider different options for consistent funding and delivery of assessor forums and will report at NELAC 9.	NELAC 9
4.	Committee will consider changes to Chapter 3 in response to comments received at NELAC 8i and will propose any changes on which the committee reaches consensus for vote at NELAC 9.	NELAC 9

**PARTICIPANTS  
ON-SITE ASSESSMENT COMMITTEE MEETING  
NOVEMBER 19, 2002**

<b>Name</b>	<b>Affiliation</b>	<b>Address</b>
Alfredo Sotomayor, Chair	Wisconsin Department of Natural Resources	T: (608)266-9257 F: (608)266-5226 E: Alfredo.Sotomayor@dnr.state.wi.us
Charles Dyer	New Hampshire Dept. of Environmental Services	T: (603)271-2991 F: (603)271-2997 E: cdyer@des.state.nh.us
Jack Hall (Absent)	Interpretive Consulting	T: (865)576-4138 F: (865)576-8558 E: scl3883@aol.com
Daniel Hickman (Absent)	Oregon DEQ Laboratory	T: (503)229-5983 F: (503)229-6924 E: hickman.dan@deq.state.or.us
William Ingersoll	US Navy - NAVSEA Programs	T: (843)764-7337 F: (843)764-7360 E: ingersollws@navsea.navy.mil
Marlene Moore	Advanced Systems, Inc.	T: (302)368-1211 F: (720)293-3706 E: mmoore@advancedsys.com
Faust Parker	PBS&J Env. Toxicology Lab	T: (713)977-1500 ext. 114 F: (713)977-9233 E: frparker@pbsj.com
Frederic Siegelman	USEPA/OEI	T: (202)564-5173 F: (202)565-2441 E: siegelman.frederic@epa.gov
Santos Urrea	City of Austin Water & WW Utility	T: (512)927-4027 F: (512)927-4038 E: santos.urrea@ci.austin.tx.us
Allen Verstuyft	Chevron Texaco ERTC	T: (510)242-2403 F: (510)242-1792 E: awve@chevrontexaco.com
Owen Crankshaw (Contractor Support)	RTI	T: (919)541-7470 F: (919)541-7386 E: osc@rti.org
Lisa Greene (Contractor Support)	RTI	T: (919)541-7483 F: (919)541-7386 E: lcg@rti.org